White Paper:
Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland

Response to Written Comments Received on the Staff Recommendations

MARYLAND HEALTH CARE COMMISSION

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II. INTRODUCTION

At the September 15, 2000 meeting, the Commission considered staff recommendations on key issues identified in the *White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland*. (Appendix 1 to this memorandum provides the staff recommendations released for public comment.) Those staff recommendations, which will provide the basis for drafting proposed permanent regulations to update the State Health Plan chapter, were prepared after analysis of extensive written public comments received on the White Paper. Following the September meeting, the Commission invited interested organizations to submit comments on the staff recommendations by October 6, 2000. The purpose of this paper is to summarize and analyze the public comments received on the staff recommendations.

II. SUMMARY AND ANALYSIS OF PUBLIC COMMENTS

In response to the Commission's invitation, nine organizations submitted comments on the staff recommendations: (1) Adventist HealthCare; (2) Dimensions Healthcare System; (3) Holy Cross Hospital; (4) Johns Hopkins Medicine; (5) LifeBridge Health; (6) MedStar Health; (7) Montgomery County Commission on Health; (8) St. Agnes HealthCare; and (9) Suburban Hospital. The summary and analysis of public comments is organized to correspond to the policy options identified in the White Paper: Need Projection Policies; Quality of Care Policies; Cost of Care Policies; Access to Care Policies; and Other Policies.

A. Need Projection Policies

1. Definition of Planning Regions

Summary of Public Comments. Comments from the Montgomery County Commission on Health indicated their disappointment that Montgomery County was included in the Metropolitan Washington region for planning cardiac surgery services. Those comments stated that use of the regions in the current State Health Plan would appear to preclude any new programs in the metropolitan Washington region.

Staff Analysis and Recommendation. The current State Health Plan chapter establishes four regional service areas for planning adult cardiac surgery services: Western Maryland; Metropolitan Washington; Metropolitan Baltimore; and Eastern Shore. The Metropolitan Washington region includes Montgomery County as well as five other jurisdictions (Washington,

D.C. and the Maryland counties of Prince George's, Calvert, Charles, and St. Mary's). The proposed need projection included in the staff recommendations does not preclude the development of a new program in the Metropolitan Washington region. In fact, the need projection included in the staff recommendation identifies need for a new cardiac surgery program in the Metropolitan Washington region. Staff believes that the four regions used for planning cardiac surgery in the current State Health Plan are appropriate for use in the update of the chapter.

2. Length of Planning Horizon

Summary of Public Comments. The length of the planning horizon was addressed by one commenter. Comments submitted by Holy Cross Hospital suggested that a five-year planning horizon be used for the State Health Plan. While Holy Cross Hospital agreed that the treatment of heart disease is changing rapidly, they suggested that this change be reflected in frequent updates of the need projection rather than a shorter planning horizon.

Staff Analysis and Recommendation. Traditionally, the State Health Plan has used a five-year horizon for planning the future development of health services and facilities. In the State Health Plan chapter on Cardiac Surgery and Therapeutic Catheterization Services, a shorter three-year planning horizon was first used with the update of the chapter that became effective December 1, 1997. A five-year planning horizon was used in the prior cardiac surgery plan chapter. The use of a shorter planning horizon in the current plan chapter is consistent with advice provided by the Technical Advisory Committee on Cardiovascular Services in their December 1999 report to the Commission. Given the potential for changes in the treatment of heart disease that could influence policies governing the organization of care, staff believes that the preferable policy direction is to use a three-year planning horizon in the current update of the State Health Plan. While it may be appropriate to return to a five-year planning horizon in future plan updates, staff believes that there is benefit to reassessing the need projections as well as the underlying policy assumptions based on a three-year planning horizon.

3. Use Rate Assumptions in Projecting Future Cases

No additional public comments were received on this policy.

4. Measurement of Program Capacity

Summary of Public Comments. Several organizations submitted comments addressing the issue of program capacity measurement. With respect to the definition of program capacity, Adventist HealthCare indicated that the staff recommendations regarding program capacity were unsupported. Without any findings, rationale, support from the Technical Advisory Committee or other basis, the staff recommendations deem, for planning purposes, that there are limits on Adventist HealthCare's capacity that do not in reality exist. According to Adventist HealthCare, there is no rationale offered for a finding that the hospital could not handle a greater number of cases, if this were needed. The recommendations presume that historical utilization reflects capacity, which is not based on any research, expert recommendation or other similar basis. In fact, it ignores the fact that programs such as Washington Hospital Center have historical

numbers of open-heart surgery cases in excess of the capacity figure that has been assigned to it under the staff's proposed new formula. The comments from Adventist HealthCare suggested that prudence would dictate that if a more comprehensive measure of capacity has not yet been developed, the existing, approved measure of capacity should be retained. The capacity calculation in the State Health Plan should not change until the evaluation of relevant factors, recommended by the Technical Advisory Committee, is conducted.

In commenting on the measurement of capacity, Dimensions Healthcare System noted that limiting the capacity measure of a program to the greater of 800 or of 50 percent of gross need for the planning region is a radical departure from the past practices of the Commission that has no justification in the Commission's statute or in logic. The sole purpose of the capacity measure appears to be to remedy the alleged concentration of procedures at the Washington Hospital Center. According to Dimensions Healthcare System, the statute authorizing the creation of the Commission does not give the Commission the mandate to deal with market concentration. The Washington region, despite the presence of several large programs, is not significantly more concentrated than the Baltimore region. The appearance of excessive concentration of services in Metropolitan Washington essentially is an artifact of the designated planning regions which excludes one major and two smaller programs in Northern Virginia.

Comments provided by Holy Cross Hospital and Suburban Hospital suggested two modifications to the staff recommendation concerning the measurement of program capacity. First, Holy Cross and Suburban suggested that the cap on a program's capacity by applied to a health system as a whole –i.e., the cap should be applied to the sum of the capacities at Georgetown and the Washington Hospital Center. Second, Holy Cross and Suburban indicated that the maximum share should be capped at 40 percent rather than 50 percent. Holy Cross also noted that in their view residents of the metropolitan Washington area have fewer choices than Baltimore and that the Commission should adopt policies that correct that reality, even if it means that more than one program should be approved in the next CON round. Suburban Hospital noted that it is illogical to exclude Fairfax Hospital when defining the Washington health planning region for cardiac surgery but then include it in assessing available options for residents of that same area.

While LifeBridge Health indicated that they were pleased that the recommendations implicitly acknowledge the fact that Central Maryland has more than adequate cardiac surgical capacity, and that the initiation of additional programs in this region would serve to dilute quality, they expressed concern about the capacity definition. In their view, defining capacity in terms of the number of cases a facility has performed in the past, rather than the number of cases that the facility would readily perform in the future, reflects a fundamental misapprehension of what "capacity" is supposed to measure and ignores the readily of hospital operations. In the real world, a facility's historic volumes are by no means viewed as the upper limit of its capabilities. According to LifeBridge Health, in a time of scarce human resources, it is obviously far easier for existing programs to keep the lights on a few more hours per day than it is to develop a new program from scratch, and it is precisely this ability that the term "capacity" is supposed to measure.

In comments regarding the measurement of program capacity, MedStar Health noted that the "approved facility" capacities would range from 50 to 2,126 cases per year in the metropolitan Washington area. According to MedStar Health, the Commission "approved" capacities for existing programs could be lower than the proposed minimum and threshold volume standards and would be inconsistent with the general intent of the volume standards. MedStar Health also noted that by equating utilization with capacity, the staff has created a standard that will always be a moving target. Capacity would rise and fall in time with a program's volume. MedStar believes that capacity should be defined as the potential number of cases a facility can reasonably accommodate. Capacity should be a measure of what can be accomplished, not a function of what the Commission feels should be accomplished. MedStar believes that the current operating room capacity standard of 500 cases is appropriate and achievable in efficient, high-volume programs. MedStar Health also indicated that the limitation or cap on capacity is an arbitrary manipulation of the need methodology. The purpose of the cap seems to be to create need in the metropolitan Washington area under the guide of addressing the dysfunctional characteristics of the metropolitan Washington market. It is unfair for the Commission to create need simply because market share is in excess of an arbitrary level. It is MedStar's belief that controlling market share of programs goes beyond the statutory authority of the Commission. MedStar Health believes that there is no compelling state interest in capping the market share that can be justified on state health planning grounds. To the contrary, a compelling case could be made that concentrating volume in fewer high volume centers would improve the quality and cost of care. What you see in the Washington Metropolitan region is typical of free market competition where quality and price drive referral preferences. It is no mere coincidence that nearly 37 percent of Washington's cardiac patients are residents from other regions. Proposals of new programs advance assumptions about patients wanting cardiac programs closer to their homes, but these assumptions are not supported by the evidence.

Finally, comments from Montgomery County Commission on Health noted that the new measurement of system capacity could help Montgomery County meet its demand for new cardiac services.

Staff Analysis and Recommendation. In the State Health Plan adopted in 1990, the capacity of existing cardiac surgery programs was defined as follows: the greater of 350 cases per hospital or the highest actual annual volume ever attained by the hospital in the most recent years of accurate available data; or if the hospital had not performed, for the past three consecutive years, at least 200 cases per year, the capacity of that program was measured by the actual volume of cases performed in that hospital during the base year.

The benchmark used to quantify available system capacity in the current State Health Plan reflects the number of operating rooms dedicated to the open heart surgery program. The measurement of the number of open heart surgery cases that can be performed in a single dedicated operating room used in the current plan reflects the assumption that 2.0 cases per day per operating room or 500 cases annually (assuming 5 days per week/50 weeks per year = 250 days) is a reasonable benchmark. This level of utilization is 80 percent of the defined capacity of 2.5 open heart surgery cases per day in a dedicated operating room recommended by the Technical Advisory Committee in 1997.

For the State Health Plan update, staff has recommended that the Commission consider a modified approach to measurement of cardiac surgery program capacity. For new programs, under this proposed approach, capacity would be defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence. For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint. The capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region.

Comments received on the measurement of program capacity suggested that the upper limit of capacity be lowered from 50 to 40 percent of gross need, that the Washington Hospital Center and Georgetown University Hospital be considered one program in calculating available capacity, that it was inappropriate for the Commission to "approve" capacity calculations below accepted minimum and threshold utilization standards, that it was inappropriate for the Commission to consider market share in addressing the issue of capacity, and that the capacity calculation should not be changed until a more comprehensive measure is developed. In addition, it was noted that no data were provided to suggest that Marylanders use Fairfax Hospital in substantial numbers.

The program capacity definition suggested by staff includes an upper limit for an individual hospital that is calculated based on a proportion of the projected gross need for the planning region. While the staff recommendation that this calculation reflect 50 percent of gross need may be conservative, use of a higher proportion (50 rather than 40 percent) does not change the outcome of the need projection calculation (i.e., that a new program should be considered only in the metropolitan Washington region). Given that the measurement of capacity has not previously considered program size, staff believes that it is appropriate to use the 50 percent level. Staff also believes that it is appropriate and consistent with other planning policies to apply the measurement on an institution-specific basis. The recommended three-year planning horizon provides the opportunity to assess the impact of this modified capacity measure and make any necessary adjustments within a relatively short period of time. With respect to the comment suggesting that it is inappropriate for the Commission to consider market share in addressing the issue of capacity, staff would point out that planning policies governing program size are not unreasonable and clearly not outside the scope of the Commission's mandate. Staff also does not believe that reflecting the fact that there are low volume programs in the metropolitan Washington area in measuring program capacity condones that fact. With respect to use of Virginia hospitals, available data indicates that 147 Maryland residents underwent open heart surgery in Virginia during fiscal year 1999. Ninety (90) of those Maryland residents had surgery at Fairfax Hospital. In comparison, 89 Virginia residents undergoing open heart surgery were served in Maryland programs in 1999. In summary, staff believes that the proposed measurement of program capacity reasonably and appropriately balances public policy concerns.

5. Patient Migration Patterns

Summary of Public Comments. Comments submitted by Holy Cross Hospital stated that they continued to believe that county-specific, rather than region-wide, migration patterns should

be used because, within each region, both the county-specific migration patterns and the county-specific population growth patterns differ significantly. Holy Cross suggested that staff gave no reason for rejecting their more precise methodology.

Staff Analysis and Recommendation. The current methodology used to forecast projected open heart surgery cases assumes that existing regional patient migration patterns will remain constant between the base and target years of the forecast for all regions except Western Maryland. For in-migration from adjacent and out-of-state areas to programs in Maryland and Washington, D.C., the current methodology assumes that the actual number of patients will remain constant between the base and target years of the projection. In addition, the methodology assumes that the number of Washington, D.C. residents will remain constant between the base and target years of the need projection. Staff does not object to considering county-specific migration data in the future plan updates. Once the Western Maryland program begins operation it would be appropriate to review the current allocation system as a whole.

B. Quality of Care Policies

1. Minimum and Threshold Volume Standards

Summary of Public Comments. Holy Cross Hospital stated its support of the initial 200 OHS case minimum and 350 OHS case volume by the third year of operation. Assuming it is legal to set minimum standards for angioplasty, Holy Cross Hospital supports the 200 case minimum and no threshold for angioplasty. Holy Cross also supports the impact standard of a new program not resulting in any program falling below 350 OHS cases, so long as a program is interpreted to mean a health system. Adventist HealthCare stated support for the minimum and threshold volume standards included in the staff recommendation. In their comments on quality of care policies, Washington Adventist recommended that they have the opportunity to allocate capacity throughout their merged asset system within Montgomery County, consistent with the minimum and threshold standards, and population needs. Comments from MedStar Health indicated that the state has a compelling interest in encouraging and maintaining high-volume angioplasty programs. Although angioplasty services are not covered by CON regulations, the State does require that providers of angioplasty have cardiac surgery backup facilities. This requirement ensures that high-volume programs, which possess the expertise and resources for specialized cardiac care, are the only provider of these services. Facilities that do not have cardiac surgery programs are not likely to have cardiopulmonary equipment or experienced perfusionists available. The co-location requirement is consistent with clinical guidelines of the American College of Cardiology and the Health Care Financing Administration. The Commission's 1999 Technical Advisory Commission deemed co-location necessary. In commenting on the quality of care policies, St. Agnes HealthCare indicated support for the concept of a minimum volume standard of 200 cases annually for angioplasty, except where services are delivered as part of the C-PORT or other research project. Given the clinical selection criteria protocol constraints, it may be difficult for participating providers to meet the minimum volume standard of 200 angioplasty cases annually.

Staff Analysis and Recommendation. The current State Health Plan establishes minimum and threshold volume standards for cardiac surgical programs. One of the quality standards used

in the current State Health Plan indicates that adult cardiac surgical programs should perform a minimum of 200 cases annually to ensure quality of care. There was substantial support in the public comments received on the White Paper for maintaining this minimum utilization standard. The current State Health Plan also establishes a threshold utilization standard which indicates that the establishment of a new cardiac surgery program should permit existing programs to maintain patient volumes of at least 350 cases annually. The use of a threshold standard, in combination with the minimum utilization standard, establishes a policy of requiring programs to perform well above the minimum level of cases before considering the development of additional program capacity. The recommendations prepared by the Technical Advisory Committee in 1999 suggest that cardiac surgery programs should perform at least 350 procedures annually within three years of beginning operation, and that approval of a new cardiac surgery program should not result in any program falling below 350 cases per year.

Staff believes that the minimum and threshold utilization standards should continue to apply on an institution-specific basis. With respect to angioplasty volumes, staff concurs with the comments regarding the need the maintain high volume programs. The establishment of minimum volume standards for angioplasty programs recommended by staff recognizes the need to encourage higher volumes. The angioplasty minimum volume standard, as suggested by the Technical Advisory Committee, refers to elective and not primary angioplasty procedures.

2. Enforcement of Minimum Volume Standards

Summary of Public Comments. The comments received from Holy Cross Hospital indicated their support of the requirement for meeting minimum volume standards so long as that standard is applied to all programs, and not simply new ones.

Staff Analysis and Recommendation. The relationship between the volume cardiac surgery cases and outcome suggests strongly that as a matter of public policy programs should meet minimum utilization levels. Given the importance of this issue, staff has recommended that the Commission continue to require as a condition of Certificate of Need approval that a cardiac surgery program achieve minimum volume standards established in the State Health Plan within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. On the question of whether existing programs should be required to meet a similar standard, the staff has recommended that the Commission consider requesting a statutory change as part of its recommendations on the Certificate of Need working paper. This statutory change would provide the Commission with the ability to withdraw the Certificate of Need and authority to operate a new or existing cardiac surgery program for failure to meet adopted standards for quality of care within a specific time period.

3. Outcome Data Reporting

Summary of Public Comments. The recommendations regarding outcome data reporting were supported by Holy Cross Hospital. Holy Cross Hospital also noted in their comments that grant funds may be available to support outcome data reporting. Johns Hopkins Medicine strongly supported the recommendation to establish an Advisory Committee on Outcome Assessment in Cardiovascular Care. The comments submitted by the Montgomery County

Commission on Health also supported the recommendation to form an Advisory Committee on Outcome Assessment in Cardiac Care and asked that Montgomery County practitioners and organizations be asked to recommend members.

Staff Analysis and Recommendation. Both the earlier public comments received on the White Paper and the public comments received on the staff recommendations indicate substantial support for the concept of working to improve patient care through the collection and analysis of outcome data. Staff believes that the establishment of an Advisory Committee on Outcome Assessment in Cardiovascular Care to study and make recommendations to the Commission is the appropriate first step in this process. If grant funds become available to support this effort, staff believes that the Commission and participating hospitals should seek those funds where appropriate.

4. Co-Location of Angioplasty and OHS Services

Summary of Public Comments. While Holy Cross Hospital believes that questions of community practice standards should be decided by patients and physicians, rather than by overarching government rule, their comments noted their appreciation of the improvement in access and choice associated with the staff's proposed new research project. Holy Cross Hospital urged that the Advisory Committee on Outcome Assessment in Cardiovascular Care be balanced in terms of perspectives, which potentially would require that a majority of appointees be from outside Maryland or the District of Columbia.

The comments submitted by LifeBridge Health noted concern with the proposed research project to examine the performance of elective angioplasties at facilities that lack open heart capacity. It should never be appropriate to perform elective angioplasties in such a setting. While the percentage of procedures that need to be converted to open cases has certainly declined over the years, according to LifeBridge Health the occasional complication still arises and in those cases the availability of open heart backup can mean the difference between life and death. Any study involving the performance of elective angioplasties without open heart backup will inevitably subject patients to unnecessary risks, and LifeBridge Health does not believe that the Commission should facilitate, let along encourage, such an effort.

MedStar Health supports limited exemptions to the co-location requirement for angioplasty and open-heart surgery for the purpose of legitimate research on promising new clinical techniques. However, because of the inherent risks of any angioplasty, exempt research should be limited to a small number of cases under carefully designed, monitored, and adjudicated protocols. Informed consent should be required of all participants in order to ensure the validity of the research findings and safety of the participating. The State should only consider the option of granting exemptions to its co-location policy when there is compelling evidence that a new alternative therapy is better than the existing therapy. MedStar Health believes that in the case of elective angioplasty, an exemption to the co-location requirement is unjustified. The risk of complications of elective angioplasty are higher relative to the benefits. Staff is recommending an exemption to the co-location requirement for the C-PORT registry. In MedStar's view, registries simply report data from non-controlled studies of patients who meet certain participation criteria. Registries do not involved control groups against which to compare

outcomes. In controlled research projects, both efficacy and safety of new treatment protocols are studied. MedStar Health believes that the State should also require that research meet this standard to be eligible for an exemption to the co-location requirement. MedStar Health cautions the Commission about endorsing non-specific research projects for elective angioplasty in this update of the State Health Plan.

Staff Analysis and Recommendation. While the State Health Plan for cardiac surgery and therapeutic catheterization services requires hospitals providing coronary angioplasty services to have on-site cardiac surgical backup, the plan also includes procedures for exempting certain research projects from this policy. Under these exemption procedures, the former Health Resources Planning Commission approved a request from Johns Hopkins University to permit selected Maryland hospitals participating in the C-PORT primary angioplasty clinical trial to perform angioplasty on certain patients with acute myocardial infarction under the protocols of this research project.

Staff believes that the C-PORT project has provided the opportunity for clinical research to guide State policy of oversight and that a similar well-designed pilot program for appropriate groups of elective angioplasty patients would contribute to improved patient care and more informed decision-making. This would provide the Commission with the clinical data necessary to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgical support for certain groups of elective angioplasty patients. This research project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care. Staff also recommends that: (1) the current policy requiring angioplasty procedures to be performed in hospitals with on-site cardiac surgery be maintained in the updated State Health Plan; and (2) the existing limited exemption for primary angioplasty performed in hospitals participating in the C-PORT project be continued.

C. Cost of Care Policies

Summary of Public Comments. The comments from Holy Cross Hospital noted their support for continuation of a cost effectiveness standard. They further recommended that when the standard is modified to reflect the HSCRC's new methodology, it should also be modified to consider all forms of saving, not just the rate offer. In commenting on the cost of care policies, Adventist HealthCare noted that the State Health Plan requires a CON to be issued before all or part of a specialized open heart surgery program can be relocated. They cautioned against adopting an approach that imposes limits on the ability to facilitate system-wide rate negotiations with existing programs.

Staff Analysis and Recommendation. The current State Health Plan contains a cost-effectiveness standard that states the Commission will give preference in a comparative review to the applicant that offers the best balance between program effectiveness and costs to the health care system as a whole. Historically, this cost effectiveness standard has been used to encourage hospitals interested in establishing new cardiac surgery programs to make competitive rate offers to the Health Services Cost Review Commission. In their earlier comments on the White Paper, the HSCRC indicated that the cost-effectiveness standard encourages continued competitiveness and keeps overall costs lower for consumers. HSRCR encouraged MHCC to retain this standard.

Staff recommends that the cost effectiveness standard preference policy be continued in the updated State Health Plan. Staff believes that there is benefit to the public in encouraging applicants to make competitive rate offers as part of the Certificate of Need process if need for additional cardiac surgery capacity is identified. The specific wording of this standard will be developed in consultation with HSCRC staff to reflect recent changes to the rate setting system. Staff will also consult with HSCRC to determine other appropriate savings that should be considered. Staff does not believe that this approach would limit the ability of HSCRC to facilitate negotiations with existing cardiac surgery programs.

D. Access to Care Policies

Summary of Public Comments. St. Agnes HealthCare was a strong advocate for the development of additional access to care standards regarding the delivery of cardiac services. St. Agnes applauds the Commission for recognizing the need for further standards to measure the ability of the delivery system in Maryland to rapidly respond to the needs of the cardiac patient. St. Agnes believes that as the Commission more fully develops the regulatory language regarding this standard that specific time frames should be established as regulation to ensure that the new access standards are incorporated into the 2003 update of the State Health Plan.

Staff Analysis and Recommendation. Staff concurs with the comment from St. Agnes HealthCare regarding the measurement of access in future updates of the State Health Plan. While staff believes that it is appropriate to continue using a travel time standard for elective cardiac surgery and angioplasty in the State Health Plan, there is a need to consider developing other access measures, including time to treatment goals for certain sub-sets of patients. One of the issues that should be addressed by the Advisory Committee on Outcome Assessment in Cardiovascular Care is the optimum timeframe for initiating primary angioplasty given current research and clinical practice. The work of this Advisory Group would provide the basis for developing additional access standards for incorporation in the 2002-2003 update of the State Health Plan.

E. Other Policies

1. Eligibility to Meet New Need

Summary of Public Comments. Holy Cross Hospital fully supports this very important standard. Comments from Adventist HealthCare indicated that the recommendation to prohibit existing programs from meeting newly identified need for all practical purposes is a recognition that any truly new "need" does not really exist in the health care system. Allowing existing programs to meet additional need would simply recognize that those programs have the capacity to handle these cases. It is only by taking capacity away from existing programs that a new "need" can be established for planning purposes that can then be met by hospitals without open heart surgery programs. According to Adventist HealthCare, if there were a true need for additional cases, the Commission would identify it, offer all those hospitals with the ability to meet that need the opportunity to demonstrate how or why they should be selected, including existing programs, and make a determination based on the proposals made. In fact, based on

available data, there are not a minimum number of "new" cases projected for the Metropolitan Washington region that would support a "new" program in 2002. Instead, what is characterized as a "need" projection is actually a formula that assumes existing cases should be redirected by state government away from currently functioning programs in the region to other hospitals in the region. LifeBridge Health suggested that the Commission ensure that the final rules give existing providers a fair opportunity to show that they can meet new need in a manner that best serves the citizens of Maryland. According to LifeBridge Health, to rule that when demand increases that only hospitals without open heart surgery programs may seek authority to meet that need would suggest that satisfying the "have nots" takes priority over the Commission's legislative mandate to balance cost, access, and quality.

Staff Analysis and Recommendation. Only hospitals without existing cardiac surgery programs are eligible to apply to meet new need under the current plan. In other words, if the need projection calculation identifies a net need that is not less than the minimum utilization standard (i.e., 200 cases) then the Commission may consider the establishment of a new program. At the same time, it is important to recognize that the identification of net need does not require that the Commission approve a Certificate of Need for a new cardiac surgery program. Staff would also point out that under current law, the Commission regulates the number rather than the size of cardiac surgery programs. Given that the number of cardiac surgery operating rooms is not regulated under the Certificate of Need program, it could be argued that existing providers have the ability to expand services to meet new need without restriction. Staff recommends that the current policy of limiting the eligibility to meet identified new need for cardiac surgery services to hospitals without existing programs be continued in the updated State Health Plan.

2. Hospital Size

Summary of Public Comments. Comments provided by Holy Cross Hospital suggested that greater size (i.e., ADC of 200 of more) be treated as a preference item, rather than simply a minimum threshold. Comments from Suburban Hospital suggested that the current standards relating to a hospital's size (i.e., average daily census and staffed ICU beds) be eliminated. Suburban Hospital also stated their objection to the recommendation to develop a new standard based on the size of a hospital's cardiology program. Suburban Hospital believes that a hospital's size, whether measured by licensed beds, ADC, or staffed ICU beds, is unrelated to the hospital's ability to operate a successful cardiac surgery program.

Staff Analysis and Recommendation. Under the current State Health Plan, applicants for new cardiac surgery programs must have an average daily census of 100 patients over the past two years and an 8-bed fully staff ICU. The current State Health Plan also permits the Commission to consider evidence as to why this policy should be waived. Data for the 12-month period ending in February 2000 indicates that 31 of the 47 licensed acute care hospitals in the State had an average daily census of 100 or more patients. Under this policy, most of the hospitals in the State would be eligible to develop a new cardiac surgery program if need were identified in the State Health Plan. An alternative approach outlined in the White Paper would be to increase the facility size policy by requiring potential new applicants for cardiac surgery programs to have an average daily census of 200 rather than 100 patients. This policy would

limit the number of hospitals that would be eligible to apply for a new open heart surgery program to the larger facilities. Eleven of the 47 acute care hospitals in the State, including 7 of the 8 Maryland open heart surgery programs, had an average daily census of 200 or more patients during the 12-month period, March 1999-February 2000.

While the size of the hospital alone would not determine the success of an open-heart surgery program, staff believes that there are advantages to having an infrastructure that can support a higher volume program. Hospital bed size is one indicator of infrastructure that would potentially have relevance in considering the development of open heart surgery programs. Staff believes that the use of the higher standard (i.e., ADC of 200) may be unnecessarily restrictive whether considered as an approval policy or a preference standard. Staff continues to believe that there are other factors that have significance, including the volume of cardiac patients currently treated within the hospital, that should be incorporated in the updated plan.

Staff recommends that the Commission: (1) continue to require applicants for new cardiac surgery programs to have an average daily census of at least 100 patients; (2) delete the policy pertaining to the size of the intensive care unit; and (3) develop indicators pertaining to the volume of cardiac patients for inclusion in the State Health Plan. With respect to the Size of Hospital policies, staff believes that the Commission should retain the ability to consider evidence as to why these policies should be waived.

3. Number of New Programs

Summary of Public Comments. Holy Cross Hospital believes that the number of new programs allowed should be based upon the net need. Contrary to staff's argument, new programs do not primarily compete with each other. In the metropolitan Washington region, all new programs will essentially compete with the Washington Hospital Center, largely by retaining the patients now referred to the Washington Hospital Center. MHCC should not now compound the error of MHRPC by imposing artificial, and very costly, limits. As noted earlier, Holy Cross will take part in the CON process, even if it is limited to one awardee, but the resources consumed by the process could be much better used for patient care.

In their public comment submission, Adventist HealthCare argues that the State Health Plan should recognize that they are able to file a CON application for the reconfiguration of existing program capacity within its system and that this is not a "new" program. According to Adventist HealthCare, if Washington Adventist Hospital has no regulatory limit to its current ability to perform open heart surgery, then no basis has been articulated for preventing Adventist HealthCare and its open-heart surgery team from using that capacity to the maximum benefit of the population it serves through both of its hospitals in Montgomery County. Adventist HealthCare believes that there is no need for a new program in the region. However, if the Commission determines one or more hospitals in the region should have a new program in a location where none exists, in order to improve access, for example, this determination should not limit an existing system from using its unused capacity to improve access. While it has been recommended that the State Health Plan maintain the requirement that a merged asset system may reconfigure existing open heart surgery services and capacity within its system with CON approval, Adventist HealthCare believes that a merger and consolidation filing should be

sufficient, since this also requires an analysis and vote by the Commission. However, Adventist HealthCare believes that even if a CON requirement is maintained, reconfiguration of existing capacity is not, and should not be, treated as the establishment of a "new" program. According to Adventist HealthCare reconfiguration of open heart surgery capacity would not have an impact on the ability of other hospitals to apply for CON approval to meet new identified need, and would not diminish the amount of newly identified need. The negative consequences of multiple "new" programs, that support the State Health Plan's prohibition on the multiple new program approvals, do not occur when a merged hospital system reconfigures existing capacity within a county. In summary, Adventist HealthCare indicated that given the purpose of approving one "new" program at a time is intended to avoid deleterious effects on other providers and allow a new provider a reasonable chance to succeed in program development, it is evident that this concern is not relevant to reconfiguration within a merged hospital system, where the incentives are inherently aligned consistent with those principles. Adventist HealthCare believes that the State Health Plan should state that reallocations of capacity within a merged health system and within a single county are not considered "new" programs and are permitted.

Staff Analysis and Recommendation. The current State Health Plan includes a policy that permits the Commission to approve only one new open heart surgery program at a time in a regional service area. Comments opposed to the current policy indicated that if need were sufficient to support more than one new program that it would be inappropriate to artificially limit the number of programs approved. In addition, comments submitted by Washington Adventist Hospital suggested that reallocations of capacity within a merged health system and within a single county should not be considered "new" programs.

The policy providing that only one new program will be approved at a time in each regional service area recognizes the importance of ensuring that cardiac surgery programs meet utilization standards. Although the impact of a new program competing with existing versus other new programs can be debated, it is would seem clear that multiple new providers would potentially negatively impact critical staffing issues. Cardiac surgery services depend on a highly trained team that includes critical care nurses, specialized operating room nurses, and perfusionists. If multiple new programs compete at the same time for the limited number of specialized nurses available, the outcome would likely be disruption to existing cardiac surgery services and additional costs to the health care system. The Association of Maryland Hospitals and Health Systems has characterized the current situation as the most severe nursing shortage in more than a decade in Maryland.[1] Given the three-year planning horizon recommended for the plan, staff believes that there are advantages to maintaining the one at time approach. In this manner, emerging trends in the utilization of cardiac services can be monitored and reflected in future updates of the need projections and planning policies.

Adventist HealthCare believes that reconfiguration of existing capacity is not, and should not be, defined as the establishment of a "new" program. According to Adventist HealthCare, reconfiguration of open heart surgery capacity would not have an impact on the ability of other hospitals to apply for CON approval to meet new identified need, and would not diminish the amount of newly identified need. Staff would point out that if every hospital that is a member of

[1] MHA: The Association of Maryland Hospitals and Health Systems, *Health Matters*, Maryland Facing A Shortage of Nurses, Fall 2000, Vol. 1, No. 4.

a merged asset system were able to establish an open heart surgery program based on this principle, the number of open heart surgery programs in Maryland would more than double, none of which would be considered "new" capacity. The argument that reconfiguration of existing program capacity to another hospital within a merged asset system should not be considered a "new" program would clearly undermine the intent of the policy and the principles of regional planning for highly specialized services.

4. Preference Standards in Comparative Reviews

Summary of Public Comments. Holy Cross Hospital supports the preference standards designed to promote cardiovascular disease prevention and outreach to minority populations. Holy Cross questions the preference for research in cardiovascular disease given that no guidance has been provided regarding the need that research be substantial, original, etc. St. Agnes HealthCare supported the concept of preference standards in relation to the review of CON applications to meet new need. St. Agnes was pleased to see the inclusion of standards directly related to the experience of a provider in the delivery of cardiovascular care across the continuum from prevention to participation in cardiovascular research. St. Agnes believes that the preference standards should be expanded to include prior experience with primary angioplasty through the C-PORT or other research projects. Suburban Hospital supported the recommendation to develop a preference standard for research. Suburban believes that the standard should prefer an applicant whose open heart surgery program will include a research, training, and education program of national significance. Comments provided by the Montgomery County Commission on Health stated that they are committed to employing preference standards designed to promote cardiac disease prevention and outreach to minority populations. They also endorsed the policy which permits flexibility for the Commission to consider innovative research projects involving emerging technology.

Staff Analysis and Recommendation. The preference standards in the State Health Plan provides the Commission with a tool for encouraging prospective applicants to address important health policy issues. The current State Health Plan includes standards that give preference to applicants with an established cardiovascular disease prevention and early diagnosis program that includes provisions for educating patients about treatment options; and applicants with an established cardiovascular disease prevention and early diagnosis program with particular outreach to minority and indigent patients in the hospital's regional service area. In the area of cardiac care services, for example, use rates for African-Americans have historically been well below those experienced by the non-African American population. While the precise reasons for these differences are not well understood, giving preference to applicants with a demonstrated record of serving minority populations may provide positive results in reducing the disparity in use rates. Staff recommends that the preference standards designed to promote cardiovascular disease prevention and outreach to minority populations be maintained in the updated State Health Plan. In addition, staff believes that the updated State Health Plan should include a preference standard designed to recognize experience with and encourage participation in research of local and national significance in the area of cardiovascular diseases. The comments submitted by Suburban Hospital broaden this preference to include education and training. Staff does not object to expanding the preference to encompass research, education, and training. Given the benefits of the C-PORT project to Maryland, staff continues to believe that research,

education, and training projects of both local and national significance should be considered within this standard.

5. Exemption from State Health Plan Policies

No additional public comments were received on this policy.

6. Relocation of Existing Cardiac Surgery Capacity within Merged Asset Hospital Systems

Summary of Public Comments. Holy Cross Hospital strongly supports this important policy. While it has been recommended that the State Health Plan maintain the requirement that a merged asset system may reconfigure existing open heart surgery services and capacity within its system with CON approval, comments from Adventist HealthCare suggested that a merger and consolidation filing should be sufficient, since this requires an analysis and vote by the Commission.

Staff Analysis and Recommendation. Because the potential relocation or dividing of cardiac surgery programs may result in proliferation of programs in the absence of need and undermine the principles of regional planning for highly specialized services, the policies in the current State Health Plan prohibit the relocation of all or part of an existing cardiac surgery program within a merged asset system without obtaining a Certificate of Need. Given the small number of programs offering cardiac surgery, it seems appropriate that changes in the location of those programs be the subject of a full Certificate of Need review. Staff believes that the Commission should maintain the policy that a merged asset hospital system may not relocate any part of an existing cardiac surgery program to another hospital within its system without obtaining a Certificate of Need.

7. Other Issues

•Docketing Rules

Summary of Public Comments. Suburban Hospital noted that the 1997 State Health Plan chapter states that an application to develop an open heart surgery program will be "docketed" (i.e., accepted for review) only if certain threshold standards are satisfied. Suburban proposes that the docketing rule prohibiting new program development if any existing program performs fewer than 350 cases per year be eliminated. Application of this rule would prohibit development of a new Maryland-based program in the Washington region because there are four chronically low-volume programs which have not met the 350-case threshold for many years, even though the region's overall volume has grown considerably.

Staff Analysis and Recommendation. The current State Health Plan includes policies that require new adult cardiac surgery programs to perform a minimum of 200 cases annually. The plan also requires existing programs to have reached 350 cases annually before considering the establishment of a new program. However, the plan does provide an exception to that rule in the case that an existing program in the regional service area has not met the 350 case volume

standard for the past two consecutive years of operation. Given that the low volume programs in the metropolitan Washington area have not met the 350 volume threshold for two consecutive years, this standard has been satisfied. Therefore, application of this standard would not preclude development of a new Maryland-based program in the Washington region. Staff does not believe that this docketing rule should be eliminated.

- **Preference for Special Missions**

Summary of Public Comments. The comments submitted by Dimensions Healthcare noted some hospitals have a mission for which a cardiac surgery program is of special importance. Specifically, university teaching hospitals, designated trauma centers, hospitals with a special mission to the poor and to minorities, and merged systems which require a program to complete the continuum of care, according the Dimensions Healthcare, should receive special consideration in the planning process and CON process for cardiac surgery. They indicated that the Commission should not approve new programs which have the potential to disrupt existing programs at special mission hospitals.

Staff Analysis and Recommendation. Staff believes that the existing Certificate of Need process provides the ability to address the important issues identified in the comments from Dimensions Healthcare. Under COMAR 10.24.01, the Commission is required to consider the impact of a new program on existing providers. As part of this analysis, an applicant is required to provide information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, including the impact on geographic and demographic access to services, on occupancy when there is a risk that this will increase costs to the health delivery system, and on costs and charges of other providers.

III. STAFF RECOMMENDATION

The staff recommendations on the policy issues involved in updating the State Health Plan: Cardiac Surgery and Therapeutic Catheterization Services are summarized in Table 1. Following Commission consideration of these recommendations, staff will draft proposed permanent regulations for consideration at the November public meeting.

Table 1
State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services:
Summary of Staff Recommendations on Policy Issues

Policies	Staff Recommendation
A. Need Projection Policies	
(1) Definiton of Planning Regions	Four regional service areas (Western Maryland, Metropolitan Washington, Metropolitan Baltimore, Eastern Shore) used in current SHP
(2) Length of Planning Horizon	Three-Year Planning Horizon
(3) Use Rate Assumptions in Projecting Future Cases	1997-1999 Trended, Regional Use Rates (With adjusted data for George Washington University Hospital)
(4) Measurement of Program Capacity	a. For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence. b. For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint. c. The capacity of any program cannot be greater than the higher of 800 caes or 50 percent of the projected gross need for the planning region.
(5) Patient Migration Patterns	Constant Patient Migration Patterns Between Base and Target Years
B. Quality of Care Policies	
1. Minimum and Threshold Utilization Standards	
(a) Cardiac Surgery-Minimum Utilization Standard	200 Cases Annually
(b) Cardiac Surgery-Threshold Utilization Standard	350 Cases Annually
(c) PTCA-Minimum Utilization Standard	200 Elective Cases Annually
(d) PTCA-Threshold Utilization Standard	None
2. Enforcement of Minimum Volume Standards	Enforce for New Cardiac Surgery Programs as Condition of CON Approval
3. Outcome Data Reporting	Establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to: (1) review available models and develop recommended approaches to outcome measurement in cardiovascular care, including cardiac surgery and angioplasty services; (2) develop a research agenda to advance the understanding of how cardiac care services should be organized to imporve outcomes; and (3) develop recommendations on the appropriate goverance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care.
4. Co-Location of Angioplasty and Open Heart Surgery	Maintain Current Policy Requiring On-Site Cardiac Surgery for Angioplasty Procedures with Limited Exemption for Primary Angioplasty; Establish Pilot Project to Assess Policy Regarding On-Site Cardiac Surgery Support for Selected Groups of Elective Angioplasty Patients

C. Cost of Care Policies **1. Cost Effectiveness Standard**	Give Preference in Comparative Review to Hospital with the Most Advantageous Rate Offer to the State
D. Access to Care Policies **1. Travel Time**	a. 2 Hours, One-Way Driving Time for 90 Percent of the Maryland Population. b. Develop Additional Access Standards Based on Work of the Advisory Committee on Outcome Assessment in Cardiovascular Care
E. Other Policies **1. Eligibility to Meet Identified New Need**	Limit Eigibility to Meet Identified New Need for Cardiac Surgery Services to Hospitals Without Existing Programs
2. Hospital Size	a. Require Applicants for New Cardiac Surgery Programs to Have an ADC of Least 100 b. Delete ICU Size Policy c. Develop indicators Pertaining to the Volume of Cardiac Patients
3. Number of New Programs Allowed	Permit One New Cardiac Surgery Program at a Time in Each Regional Service Area
4. Preference Standards in Comparative Reviews	Give Preference to Applicants Demonstrating Service to Minority and Indigent Populations; Having an Established Cardiovascular Disease Prevention Program; and Having a Research, Education, and Training Component that Addresses Issues of National and Local Significance
5. Exemptions from State Health Plan Policies	Provide that the Full Commission May Waive Policies in the State Health Plan for Research Projects for a Limited Time with Conditions
6. Relocation of Existing Cardiac Surgery Capacity	Merged Asset Hospital Systems May Not Relocate Any Part of an Existing Cardiac Surgery Program to Another Hospital within its System without Obtaining a CON

Appendix 1

Policy and Regulatory Issues in Planning Open Heart Surgery Services: Staff Recommendations

(Released for Public Comment September 15, 2000)

Policy and Regulatory Issues in Planning Open Heart Surgery Services: Staff Recommendations

(Released for Public Comment September 15, 2000)

A. Need Projection Policies

1. Definition of Planning Regions

Staff believes that the four regions used for planning cardiac surgery in the current State Health Plan continue to appropriately recognize physician referral and patient migration patterns for specialized cardiovascular care services.

2. Length of Planning Horizon

One of the key issues in planning for the system of specialized cardiac care services is to assess the likely impact of trends that will shape the future environment. Given the potential for changes in the treatment of heart disease that could influence the organization of care, staff believes that the preferable policy direction is to use a three-year planning horizon in the update of the State Health Plan.

3. Use Rate Assumptions in Projecting Future Cases

The differences in use rates for adult open heart surgery services across planning regions suggest strongly that it is preferable to use regional rather than statewide experience in projecting future utilization. Staff recommends that the Commission use trended, regional use rates over the three year period 1997-1999 to project need in 2002.

4. Measurement of Program Capacity

Staff believes that the comments received on the measurement of program capacity suggest that the use of either physical operating room resources or historical utilization to quantify system capacity has significant limitations. Both approaches result in at best proxy indicators for system capacity. In the absence of a more comprehensive measure, staff recommends that the measurement of system capacity be changed as follows:

a. For new programs, capacity is defined as the greater of 350 cases or the actual number of cases during the first three years of a program's existence.
b. For programs older than three years, capacity is defined as the highest actual annual volume attained and reported by that program over the last three years subject to a market based constraint.
c. The capacity of any program cannot be greater than the higher of 800 cases or 50 percent of the projected gross need for the planning region.

(Refer to Table A-6 in Appendix 2 for the calculation of capacity using this recommended definition)

5. Patient Migration Patterns

Because a large number of factors influence where patients go for cardiac care services, actual utilization experience may be the best guide to future utilization patterns in the absence of being able to anticipate the impact of specific changes. Staff recommends that the Commission continue the policy of holding patient migration patterns constant between the base and target years of the need projection. It should be noted, however, that other aspects of the need methodology, notably measurement of capacity, may result in identification of need for new programs which will alter migration patterns in the future.

B. Quality of Care Policies

1. Minimum and Threshold Volume Standards-Open Heart Surgery and Coronary Angioplasty

For cardiac surgery services, a large volume of research studies have suggested lower mortality rates for programs performing higher volumes of procedures. Staff recommends cardiac surgical programs be required to perform a minimum of 200 cases annually to ensure quality of care; that programs be required to perform at least 350 procedures annually within three years of beginning operation; and that approval of a new cardiac surgery program not result in any program falling below 350 cases per year.

For angioplasty services, research studies have suggested improved outcomes for programs performing higher volumes of procedures. Staff recommends that angioplasty programs be required to perform a minimum of 200 cases annually to ensure quality of care.

2. Enforcement of Minimum Volume Standards

The relationship between the volume cardiac surgery cases and outcome suggests strongly that as a matter of public policy programs should meet minimum utilization levels. Given the importance of this issue, staff recommends that the Commission continue to require as a condition of Certificate of Need approval that a cardiac surgery program achieve minimum volume standards established in the State Health Plan within 24-months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. On the question of whether existing programs should be required to meet a similar standard, the staff will make a recommendation on whether to change the current statute as part of its recommendations on the Certificate of Need working paper.

3. Outcome Data Reporting

Staff recommends that the Commission establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to: (1) review available models and develop recommended approaches to outcome measurement in cardiovascular care, including cardiac surgery and angioplasty services; (2) develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes; and (3) develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care. In establishing this Advisory Committee, the Commission should seek nominations from the Maryland Chapter of the American College of Cardiology, the Maryland Chapter of the American Heart Association, the Society of Thoracic Surgeons, the Medical-Chirurgical Faculty of Maryland, Maryland Hospital Association, and other appropriate organizations. Funding to support the work of the Advisory Committee on Outcome Assessment in Cardiovascular Care should be provided jointly by the Commission and hospitals.

4. Co-Location of Angioplasty and Open Heart Surgery Services

Staff recommends that: (1) the current policy requiring angioplasty procedures to be performed in hospitals with on-site cardiac surgery be maintained in the updated State Health Plan; and (2) the existing limited exemption for primary angioplasty performed in hospitals participating in the C-PORT project be continued. Staff believes that the C-PORT project has provided the opportunity for clinical research to guide State policy of oversight and that similar well-designed clinical research would contribute to improved patient care and more informed decision-making. Staff also believes that the Commission should consider a research project to assess whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients. This research project should be designed and implemented as a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care.

C. Cost of Care Policies

1. Cost Effectiveness Standard

If need for additional cardiac surgery capacity is identified, staff believes that there is benefit to the public in encouraging applicants to make competitive rate offers as part of the Certificate of Need process. While the specific wording of this standard must be updated to be consistent with the recent changes to the HSCRC rate setting system, the policy approach has proven viable in the past and resulted in savings to the healthcare system that might not have otherwise been realized. At the same time, staff does not believe that cost considerations should receive greater weight than quality or access considerations. The cost effectiveness standard provides the

Commission with the ability to give preference to the most cost effective applicant where other considerations in the review process are equal. Staff recommends that the cost effectiveness standard preference policy be continued in the updated State Health Plan.

D. Access to Care Policies

1. Travel Time Standard

Staff believes that it is appropriate to continue using a travel time standard in the updated State Health Plan for Cardiac Surgery and Therapeutic Catheterization Services. This standard should refer to elective cardiac surgery and angioplasty services. Staff believes that the current 2-hour, one-way driving time for 90 percent of the population is a reasonable standard. At the same time, staff recognizes the need to consider developing other access measures, including time to treatment goals for certain sub-sets of patients, as pointed out in several of the comments received on travel time. One of the issues that should be addressed by the Advisory Committee on Outcome Assessment in Cardiovascular Care is the optimum timeframe for initiating primary angioplasty given current research and clinical practice.

E. Other Policies

1. Eligibility to Meet New Need

Staff recommends that the current policy of limiting the eligibility to meet identified new need for cardiac surgery services to hospitals without existing programs be continued in the updated State Health Plan.

2. Hospital Size

Staff recommends that the Commission: (1) continue to require applicants for new cardiac surgery programs to have an average daily census of at least 100 patients; (2) delete the policy pertaining to the size of the intensive care unit; and (3) develop indicators pertaining to the volume of cardiac patients for inclusion in the State Health Plan. With respect to the Size of Hospital policy, staff believes that the Commission should retain the ability to consider evidence as to why this policy should be waived.

3. Number of New Programs Allowed

Staff recommends that the Commission continue the policy of permitting the approval of one new cardiac surgery program at a time in each regional service area.

4. Preference Standards in Comparative Reviews

From a planning perspective, the use of preference standards in a highly competitive, comparative Certificate of Need review can provide an incentive for hospitals to

address important public policy issues. For this reason, staff recommends that the preference standards designed to promote cardiovascular disease prevention and outreach to minority populations be maintained in the updated State Health Plan. In addition, the updated State Health Plan should include a preference standard designed to encourage research in the area of cardiovascular diseases.

5. Exemptions from State Health Plan Policies

The current exemption policy maintains flexibility for the Commission to consider innovative research projects involving emerging technology without compromising important planning policies. Staff recommends that this policy be incorporated in the updated State Health Plan with a modification to permit hospitals to contribute funding for research projects under appropriate circumstances. This exemption policy would provide the Commission with the ability to conduct a study on whether it would be appropriate to modify current policy regarding the availability of cardiac surgical support for certain groups of elective angioplasty patients.

6. Relocation of Existing Cardiac Surgery Capacity Within Merged Asset Hospital Systems

Staff recommends that the Commission maintain the policy that a merged asset hospital system may not relocate any part of an existing cardiac surgery program to another hospital within its system without obtaining a Certificate of Need.

Appendix 2

Calculation of Net Need for Adult Cardiac Surgery
By Regional Service Area: Target Year 2002
Staff Recommendations
(Released for Public Comment September 15, 2000)

Table A-6

Calculation of Net Need for Adult Cardiac Surgery by Regional Service Area: Target Year 2002

Hospital by Region	Existing and CON Approved Capacity	Projected Cases (2002)	Net Need (2002)	New Program Considered
Western Maryland	350	292	(58)	No
Metropolitan Washington				
Prince George's Hospital Center	120			
Washington Adventist	899			
Georgetown Univ. Hospital	328			
George Wash. Univ. Hospital	85			
Howard University Hospital	50			
Washington Hospital Center	2,126			
Total	3,608	4,251	643	Yes
Metropolitan Baltimore				
Johns Hopkins Hospital	1,146			
Sinai Hospital of Baltimore	541			
St. Josephs Hospital	1,411			
Union Memorial Hospital	893			
University of Maryland Hospital	775			
Total	4,766	4,281	(485)	No
Eastern Shore				
Peninsula Regional Medical Ctr.	561	612	51	No

Staff Recommendation

September 15, 2000